

heart, or liver, or any combination thereof, of any poultry.

[37 FR 9706; May 16, 1972, as amended at 39 FR 4568, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 48 FR 6091, Feb. 10, 1983; 49 FR 2236, Jan. 19, 1984; 49 FR 3643, Jan. 30, 1984; 49 FR 47478, Dec. 5, 1984; 51 FR 37709, Oct. 24, 1986; 64 FR 745, Jan. 6, 1999; 64 FR 56416, Oct. 20, 1999; 66 FR 1770, Jan. 9, 2001; 66 FR 22905, May 7, 2001; 67 FR 13258, Mar. 22, 2002; 69 FR 255, Jan. 5, 2004]

## Subpart B—Administration; Application of Inspection and Other Requirements

### § 381.3 Administration.

(a) [Reserved]

(b) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers of the provisions of the regulations are not in conflict with the purposes or provisions of the Act.

(c) Pursuant to section 6 of the Act, the Administrator believes that, in establishments processing poultry products at which inspection under the Act and regulations is required, the frequency with which and the manner in which poultry products made from poultry previously slaughtered and eviscerated in official establishments are reinspected by Inspection Service employees should be based on considerations relevant to effective regulation of poultry products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be deemed necessary pursuant to section 6 of the Act, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Ad-

ministrator shall identify establishments for review, and the frequency and the manner of inspection by Inspection Service employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(d) The determinations referred to in paragraph (c) of this section shall be made by the Inspection Service and shall reflect evaluations of the performance and the characteristics of such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person operating such establishment or by anyone responsibly connected with the business operating such establishment, as “responsibly connected” is defined in section 18(a) of the Act,

(ii) The competence of the person operating such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Inspection Service employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter and evisceration operations

#### § 381.4

also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Federal Meat Inspection Act also are processed at such establishment, and

(vi) The size of such establishment.

(e)(1) For the period of experimentation described in paragraph (c) of this section, the frequency of inspection by Inspection Service employees of operations other than slaughter and evisceration may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (d)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (d)(2) of this section,<sup>1</sup>

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Inspection Service employees.

(ii) To the extent that frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this part,

<sup>1</sup>These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

#### 9 CFR Ch. III (1–12 Edition)

the Administrator will waive such provisions for the period of experimentation, in accordance with paragraph (b) of this section.

[37 FR 9706, May 16, 1972, as amended at 52 FR 10033, Mar. 30, 1987; 69 FR 255, Jan. 5, 2004]

#### § 381.4 Inspection in accordance with methods prescribed or approved.

Inspection of poultry products shall be rendered pursuant to the regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

#### § 381.5 Publications.

Publications under the Act and the regulations shall be made in the FEDERAL REGISTER and in such other media as the Administrator may designate.

#### § 381.6 Establishments requiring inspection.

Inspection under the regulations is required at:

(a) Every establishment, except as provided in § 381.10 (a) and (b) or § 381.11, in which any poultry is slaughtered for transportation or sale in commerce, or in which any poultry products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food;

(b) Every establishment, except as provided in § 381.10 (a) and (b), (c), or (d), or § 381.11, within any State or organized territory which is designated in § 381.221 pursuant to section 5(c) of the Act, at which any poultry is slaughtered or any poultry products are processed, for use as human food solely for distribution within such jurisdiction; and

(c) Except as provided in § 381.10 (a) and (b), or (c), or § 381.11, every establishment designated by the Administrator pursuant to section 5(c) of the Act as one producing adulterated poultry products which would clearly endanger the public health.

#### § 381.7 Coverage of all poultry and poultry products processed in official establishments.

All poultry and poultry products processed in an official establishment shall be inspected, handled, processed,